DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
9207/d

60 8th Street, N.E.
Atlanta, Georgia 30309

December 11, 2001

VIA FEDERAL EXPRESS

WARNING LETTER
(02-ATL-13)

Robert T. Shinn, Owner
The Feed Bucket
325 West Statesville Avenue
Mooresville, North Carolina 28115

Dear Mr. Shinn:

An inspection of your operation was conducted by Food and Drug Administration Investigator Richard L. Garcia on November 14, 2001. The inspection revealed several significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000 – Animal Proteins Prohibited in Ruminant Feed (21 CFR 589.2000). This regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalophathy (BSE). These deviations cause the products being repacked and distributed by your facility to be adulterated within the meaning of Section 402(a)(4) and misbranded within the meaning of Section 403(f) of the Federal Food, Drug and Cosmetic Act (the Act).

Our inspection found that your firm failed to label feeds that contain, or may contain, prohibited materials with the required cautionary statement "Do not feed to Cattle or Other Ruminants". We suggest this statement be distinguished by different type size or color or other means of highlighting the statement so it is easily noticed by the purchaser. In fact you were selling repacked pet food (cat food) into 50-pound brown paper bags that contained no labeling at all, which further misbrands this product.

Our inspection also revealed that your customer records are not sufficient to track the distribution of products that contain, or may contain, prohibited material. Review of your receipts revealed that they failed to contain any name or address of the purchaser or identification of the product purchased.

The above is not intended to be an all-inclusive list of deviations from the regulations. As a repacker and distributor of materials intended for animal feed use, you are responsible for

ensuring that your overall operation and the products you repack and distribute are in compliance with the law. We have enclosed a copy of the FDA's Small Entity Compliance Guide to assist you with complying with the regulations.

You should take prompt action to correct these violations and you should establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to seizure and/or injunction, without further notice.

You should notify this office in writing within fifteen (15) working days of the receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations and prevent their recurrence. If corrective action cannot be taken within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Please include copies of any available documentation and labeling which demonstrates that corrections have been made.

Your reply should be directed to Philip S. Campbell, Compliance Officer, at the address indicated on the letterhead.

Sincerely,

Ballard H. Graham, Director
Atlanta District

Enclosure